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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,689	09/26/2003	Christine Schmidt	UTAU:1063	9268

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EXAMINER

FORD, ALLISON M

ART UNIT PAPER NUMBER

1651

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/672,689

Applicant(s)

SCHMIDT ET AL.

Examiner

Allison M. Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-19, drawn to a method for preparing a cell-free tissue replacement, classified in class 623, subclass 915.
- II. Claims 20-30, drawn to a native, cell-free tissue replacement, classified in class 424, subclass 422.
- III. Claims 31-40, drawn to an optimized acellular graft, classified in class 435, subclass 395.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of invention II is made by a different process than the method of invention I; for example, the method of making invention II requires the use of Triton X-200/SB-16, which is not required in the method of invention I, additionally, the product of invention II requires soaking in a sulfobetaine solution for at least about six hours, wherein the term “about” renders a much broader range than that required by the method of invention I, which only requires soaking for at least six hours.

Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the method of invention I can be used

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to make any cell-free tissue replacement, such as collagen scaffolds for bone grafting, it is not limited to only making acellular grafts for support of axonal regeneration. Additionally, the optimized acellular graft of invention III can be made by any method of preparing an acellular graft, for example, micropatterned chips for directing neuronal growth; therefore the acellular graft support of invention III can be made by methods other than that of invention I.

Inventions II and III are distinct inventions and thus are subject to restriction. The inventions are distinct in that the products are not dependent on each other, not to be used together and have different functions, modes of operation, and effects. In the instant case the cell-free tissue replacement of invention II is distinct from the acellular graft of invention III because they have different functions and are not required or intended for use together, the acellular graft of invention III is specific for use in supporting axonal regeneration, while the cell-free tissue replacement of invention II can be used for regeneration of any cell type, including scaffolds for whole organs.

Therefore, a search and examination of all inventions in one patent application would result in an undue burden. These inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classifications, and a search for one group does not require a search for another group, restriction for examination purposes as indicated is proper.

Upon the election of Invention I, the following election of species are further required:

Claim 4 is generic to a plurality of disclosed patentably distinct species of components to be adhered to the tissue replacement, comprising a cell, a polymer, a bioactive agent, and combinations thereof. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

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Furthermore, upon the election of the species of “a cell” from claim 4 a further election of species is required, as follows:

Claim 5 is generic to a plurality of disclosed patentably distinct species of cell types, comprising bone, cartilage, dermal, muscular, thyroidal, parathyroidal, lymphoid, pancreatic, urinary, digestive, hepatic, biliary, vascular, nervous, reproductive, and combinations thereof. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Alternatively, upon the election of the species of “a polymer” from claim 4 a further election of species is required, as follows:

Claim 8 is generic to a plurality of disclosed patentably distinct species of polymers, comprising naturally occurring polymers, synthetically-derived polymers, covalently crosslinkable polymers, ionically crosslinkable polymers, hydrophilic polymers, and combinations thereof. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Alternatively, upon the election of the species of “a bioactive agent” from claim 4 a further election of species is required, as follows:

Claim 7 is generic to a plurality of disclosed patentably distinct species of bioactive compounds, comprising drug, protein, peptide, polysaccharide, fatty acid, nucleic acid, oligonucleotide, detectable agent, organic molecules, inorganic molecules or salts, and combinations thereof. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Upon the election of Invention II the following election of species are further required:

Claim 21 is generic to a plurality of disclosed patentably distinct species of tissue types, comprising: bone, cartilage, dermal, muscular, thyroidal, parathyroidal, lymphoid, pancreatic, urinary, digestive, hepatic, biliary, vascular, nervous, reproductive, and combinations thereof. Applicant is

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required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 23 is generic to a plurality of disclosed patentably distinct species of components to be adhered to the tissue replacement, comprising a cell, a polymer, a bioactive agent, and combinations thereof. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 24 is generic to a plurality of disclosed patentably distinct species of components to be adhered to the tissue replacement, comprising a cell, a polymer, a bioactive agent, and combinations thereof. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Upon the election of Invention III, the following election of species is further required:

Claim 34 is generic to a plurality of disclosed patentably distinct species of components to be adhered to the tissue replacement, comprising a cell, a polymer, a bioactive agent, and combinations thereof. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that any of the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Allison M Ford
Examiner
Art Unit 1651


LEON B. LANKFORD, JR.
PRIMARY EXAMINER